In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1405V

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WILLIAM EFRON,	*	
	*	Filed: January 2, 2025
Petitioner,	*	
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
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Mark T. Sadaka, Sadaka Associates LLC, Englewood, N.J., for Petitioner.

Nina Ren, U.S. Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION[1]

On October 16, 2020, William Efron filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, as amended (the "Vaccine Program"),[2] alleging that the influenza ("flu") vaccine he received on October 20, 2017, caused or significantly aggravated his development of "cold intolerance, tremor, myalgia, fatigue and anhidrosis." *See generally* Petition. At hearing (held on two non-consecutive dates: June 4 and August 14, 2024), Petitioner primarily argued that the flu vaccine had induced anhidrosis[3] and fibromyalgia.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. Id.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

[3] Anhidrosis is defined as the "absence or severe deficiency of sweating, usually due to absence or paralysis of the sweat gland or to obstruction of the sweat ducts." *Anhidrosis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=2900&searchterm=anhidrosis (last visited Jan. 2, 2025).

Now, after review of the complete medical record as filed, expert reports, medical/scientific literature, and the parties' briefs, I deny entitlement. As explained in greater detail below, Petitioner has not preponderantly demonstrated that the flu vaccine could cause anhidrosis (the only injury that has been preponderantly established), and this condition has not been shown to have begun in a medically-acceptable post-vaccination timeframe.

I. Factual Background

Vaccination and Subsequent Six Months of Treatment

Petitioner received the flu vaccine on October 20, 2017. Ex. 3 at 1. At the time, he was fifty-four years old, and had a significant medical history which included achondroplasia,[4] obstructive sleep apnea, congenital kyphoscoliosis, [5] cervical myelomalacia,[6] and allergic rhinitis with congestion, among other things.

There is no contemporaneous record evidence of any immediate vaccine reaction or concerns. In fact, the next time Petitioner sought medical treatment occurred nearly two months later, on December 18, 2017, when he visited his primary care physician ("PCP"), Dr. Hannah Licthsinn. Ex. 5 at 4. At this time, however, Petitioner reported "intermittent[] 'flu like' symptoms since getting the flu shot," and described feeling achiness, fatigue, chills, and occasionally feeling feverish (although he did not document any fevers). *Id.* Petitioner explained that these symptoms recurred roughly every seven days, but that the most recent episode had been shorter than the prior. *Id*. A physical examination was normal, and a physician assistant ("PA") diagnosed Petitioner with unspecified fatigue and chronic seasonal allergic rhinitis, with further laboratory testing ordered (but which yielded unremarkable results). *Id.* at 4, 10.

The following month, Petitioner returned to Dr. Lichtsinn's office on January 22, 2018, complaining of more "[i]ntermittent symptoms," which "had been getting shorter in duration" but had "worsened over the week-end." Ex. 5 at 7. He further reported body aches, a mildly decreased appetite, a lack of energy, intermittently feeling "hot and cold," and had developed a sore over the

[4] Achondroplasia constitutes "the most common skeletal dysplasia found in humans, accounting for 90% of cases of disproportionate short stature. It is caused by a mutation of the fibroblast growth factor receptor 3 (FGFR3) and has an autosomal dominant inheritance. The characteristic phenotype includes rhizomelic shortening of the extremities, and affected individuals have an increased risk of mortality in early childhood and suffer from spinal pathologies into adulthood." *Achondroplasia*, National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK559263/ (last visited Jan. 2, 2025).

[5] "Kyphoscoliosis" is defined as "backward and lateral curvature of the vertebral column." *Kyphoscoliosis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=27289&searchterm=kyphoscoliosis (last visited Jan. 2, 2025).

[6] Myelomalacia is defined as the "morbid softening of the spinal cord." *Myelomalacia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32720&searchterm=myelomalacia (last visited Jan. 2, 2025.)

weekend that had resolved. *Id.* Petitioner's physical exam was again normal, but the PA who saw him ordered additional testing (the results of which were also normal), and diagnosed Petitioner with unspecified fatigue, a sore throat, chills, and body aches. Ex. 5 at 7, 10.

Petitioner consulted with an allergist at his PCP's office a month later, on February 22, 2018, at which time he described "[r]ecurrent flulike symptoms," tremors, and restless legs, and stated that he felt chilled in the examination room. Ex. 5 at 10–11. The exam was again normal, and "[t]here [were] no red flags for any significant immunodeficiency" noted by the allergist. *Id.* at 11. Petitioner's allergist also recorded immunoglobulin levels within normal limits. *Id.* at 15.

On March 15, 2018, Petitioner was evaluated by an infectious disease specialist "for management of [a] possible infection." Ex. 5 at 15. Petitioner reported a childhood history of sinus infections as well as his concern about a possible "reaction to the influenza vaccine." *Id.* Petitioner noted that his symptoms had not been associated with any fevers, and although they had persisted, his current "primary issue [wa]s feeling chilled/cold (out of proportion to what is expected for him with the current weather)." Ex. 5 at 15. Petitioner's physical exam was once again unrevealing. *Id.* at 16.

The infectious disease specialist reviewed Petitioner's symptoms and laboratory results, deeming his presentation "[d]ifficult to attribute to receipt of influenza vaccine (i.e.[, f]lu-like illness post-vaccination) given that symptoms have persisted/recurred for so long." Ex. 5 at 16. The infectious disease specialist did "consider [the] possibility of Guillain-Barre Syndrome post-influenza vaccination," but his "overall suspicion for this [wa]s low." *Id.* Additional laboratory testing was normal. *Id.* at 14–17.

On March 23, 2018, Petitioner now reported "[n]ew 'hot flashes'" to Dr. Lichtsinn's resident—explaining that the hot flashes had occurred "[a] 'few to a dozen' times per day over the past week." Ex. 5 at 20. A neurologic exam was performed and produced unremarkable results, with the exception of evidence of hyperactive deep tendon reflexes. Ex. 5 at 22. Petitioner was diagnosed with myalgia, hot flashes, pallor, and temperature intolerance. *Id.* It was documented that Petitioner had "very non-specific symptoms following [receipt of a] flu vaccine which may itself be a red herring." *Id.* The resident further noted that Petitioner "[c]ould possibly be [experiencing an] ongoing reaction to the flu shot but [it would be] highly atypical." *Id.* Further laboratory testing produced more negative results. *Id.*

On April 1, 2018, Petitioner went to the emergency room ("ER"), reporting that he had experienced right upper extremity twitching the week prior, and that the night before he had experienced "violent 'shaking' in all extremities[, and] [t]oday, he has experienced chills all day." Ex. 8 at 4. A neurologic exam revealed normal findings, however, and he was discharged. *Id.* at 4–5. Approximately one week later, on April 9, 2018, Petitioner was evaluated by neurologist Vivian Fink, M.D., who "[r]eassured [Petitioner that] at the present time [she did not see a clear neurological etiology for his complaint[s]." Ex. 5 at 32, 34–35 (documenting "[n]o clear evidence

of neurological issues"). Because Petitioner had "no significant symptoms" other than complaints of difficulty sleeping, Dr. Fink did not consider hypothalamic dysfunction to be very likely. *Id.* at 34.

That same day, Petitioner saw endocrinologist Gregory Mucha, M.D., and informed him of his chills, tremors, fatigue, and cold (not otherwise specified). Ex. 8 at 25. Petitioner further reported "significant chill and cold intolerance since receiving a flu vaccine," deeming it a possible source for his symptoms. *Id*. at 26, 28. A physical exam was normal, and Petitioner was diagnosed with cold intolerance. *Id.* Dr. Mucha later informed Petitioner (via an email sent on April 19, 2018) that his laboratory results were normal, that his brain MRI showed "[n]o evidence of hypothalamic damage," and that "[t]he exact cause of [his] chills and cold intolerance [did] not appear to be clear at this time." *Id.* Petitioner also followed up with Dr. Fink, and she echoed Dr. Mucha's impressions, noting that Petitioner's imaging showed congenital central spinal stenosis, hypoplastic clivus, and an "[i]ncidental finding of spinal cord myelomalacia" which had likely been present for several years but required additional testing to confirm. Ex. 5 at 37.

Treatment From May to October 2018

On May 18, 2018, Dr. Lichtsinn referred Petitioner to the Mayo Clinic in Rochester, Minnesota, because other treaters had "been unable to discover an etiology for his symptoms of cold intolerance[,] tremor[,] and occasional sweats" and they "ha[d] exhausted laboratory and imaging options" available to them. Ex. 5 at 41; Ex. 2 at 10. Petitioner had an initial evaluation with internal medicine specialist Rayya Saadiq, D.O., at the Mayo Clinic on June 4, 2018, where he provided a history consistent with what he had informed treaters in the past. Ex. 3 at 317–18. Although Dr. Saadiq took note of Petitioner's extensive, yet unremarkable laboratory and imaging work done at outside facilities, she did find it notable that Petitioner's recorded temperatures had been normal, especially "[d]uring [one] of the worst episodes where he presented to the emergency room [and] his temperature was at 99[°F] even though he was feeling extremely chilled." *Id.* at 319–20. Dr. Saadiq thus proposed "that his persistent fatigue may be a component of central sensitization."[7]

Dr. Saadiq ordered more tests, but the results were either unremarkable, considered a sequela of Petitioner's existing achondroplasia, or were deemed irrelevant. Ex. 3 at 205–06 (documenting unchanged re-reading of brain and cervical spine MRIs), 236 (noting negative overnight oximetry test), and 317–20. Petitioner also underwent an autonomic reflex screen test on June 21, 2018, which showed "no evidence of autonomic failure." *Id.* at 187–88. He exhibited

[7] "Central Sensitization" is defined as "a proposed mechanism for the cause of chronic pain conditions and migraine, by which nociceptors in the central nervous system become hypersensitive to stimuli as a result of tissue damage or inflammation." *Central Sensitization*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=105522&searchterm=central+sensitization (last visited Jan. 2, 2025).

normal heart rate response, normal quantitative axon reflex sweat test results at "all sites," and there was no indication of orthostatic hypotension or abnormal blood pressure responses. *Id.*

On June 22, 2018, however, Petitioner underwent a thermoregulatory sweat test ("TST"), and it revealed "global anhidrosis with hypohidrosis over the chest and forehead," and with "[m]edication effects (trazadone, [Zyrtec]) [ ] likely influencing the results." Ex. 3 at 182. The TST result write-up also noted that "[c]entral or peripheral autonomic dysfunction or chronic idiopathic anhidrosis could also cause similar findings." *Id.*

Petitioner was later evaluated by the Mayo Clinic's Center for Sleep Medicine on July 3, 2018. Ex. 3 at 164. By this time, Petitioner was reporting that "he feels cold all the time and he is unable to sleep." *Id.* Petitioner was suspected of having insomnia "secondary to his underlying medical problems." *Id.* at 169. The records from this treatment event note that Petitioner's ferritin level, while normal, was at a level that has "been associated with aggravation of" restless legs syndrome, and Petitioner was advised to start iron supplements." *Id.* at 160, 169. He also underwent a repeat TST, and it revealed "essentially unchanged" global anhidrosis which "could suggest chronic idiopathic (essential) anhidrosis, a central autonomic disorder, or autonomic cholinergic ganglionopathy." *Id.* at 155. However, "[t]he findings cannot explain cold intolerance and rather should manifest as heat intolerance." *Id.*

On July 27, 2018, Petitioner was evaluated by a Mayo Clinic neurologist, Dr. Eduardo Benarroch,[8] and resident Andrew Rodriguez, M.D., for cold sensation, intermittent tremor, fatigue, and myalgias. Ex. 3 at 132. Petitioner reported that his cold intolerance, fatigue, and myalgias developed after the receipt of the flu vaccine in 2017. *Id.* at 133. He further stated that he "often has to turn on the thermostat in his home to 80 [degrees] to stay warm," and that "he ha[d] taken his temperature during [one] of these episodes . . . [which was] as low as 96.8°F." *Id.* at 134. A neurologic exam was (again) unrevealing, however, and there was no gross lesion visible in the hypothalamus. *Id.* at 133, 135.

Dr. Benarroch's impression was cervical myelopathy and anhidrosis, but he specifically concluded that anhidrosis by itself "cannot explain [Petitioner's] symptoms." Ex. 3 at 133. Instead, Dr. Benarroch noted that "[t]he association between the lack of sweating in the thermoregulatory sweat test and [ ] normal sweating in the autonomic reflex screen suggests a potential central cause or longstanding reduction of sweat gland activity as can be seen in essential anhidrosis." *Id.* Dr. Benarroch added that a "component central sensitization cannot be excluded and [that] this should be addressed by behavioral medicine," and expressed the view that Petitioner should "[e]ngage in[] a regular aerobic exercise program to improve his fatigue that in part may reflect

[8] Dr. Benarroch is a prominent, board-certified neurologist at the Mayo Clinic, and his main areas of focus include multiple system atrophy, Lewy body disorders, and neurochemical pathology. His research centers "on alterations of neurochemically defined neuronal groups in the brainstem and hypothalamus that control homeostasis in neurodegenerative disorders." *See* Faculty, Eduardo E. Bennarroch, M.D., *Mayo Clinic*, https://www.mayo.edu/research/faculty/benarroch-eduardo-e-m-d/bio-00077636 (last visited Jan. 2, 2025).

deconditioning." *Id*. Thus, while taking into account the positive anhidrosis test results, Dr. Benarroch *did not conclude* that Petitioner's overall presentation could be explained by anhidrosis—or that its etiology was autoimmune.

Petitioner was next seen at the Mayo Clinic's Fibromyalgia and Chronic Fatigue Clinic on July 30, 2018. Ex. 3 at 90. He reiterated that his fatigue began three to four days post-vaccination, but that he was "able to carry out activities of daily living despite symptoms." *Id.* Petitioner's widespread pain index was 0/19, he had 4/18 tender points, and his symptoms severity score was 6/12. *Id.* Petitioner's treating provider concluded that he did "not currently meet [the] criteria for chronic fatigue or fibromyalgia." *Id.* at 91–92, 97–98. The next day (July 31, 2028), Petitioner underwent a cervical spine MRI, but the results did not "explain his symptoms of feeling cold or chills." *Id.*at 26; Ex. 4 at 63–65.

On August 8, 2018, Dr. Rodriguez called Petitioner to discuss his latest test results, which were deemed unremarkable. Ex. 3 at 26. He recommended Petitioner undergo a brain MRI "with [a] focus on [the] hypothalamus/pituitary[, which] would be beneficial in identifying a potential etiology of [Petitioner's] symptoms of feeling cold." *Id.* Dr. Rodriguez further explained that "central sensitization may be a cause of [Petitioner's] symptoms of feeling cold if no pathology could be identified on the brain MRI, or that his TST result may be due to essential anhidrosis." *Id.* The results of this MRI, performed on August 14, 2018, did not demonstrate any "evidence [of] pituitary adenoma or other intracranial abnormalities." *Id.* at 14; Ex. 4 at 63–65.

Petitioner followed-up with Dr. Saadiq on August 28, 2018. Ex. 3 at 19. During this visit, Dr. Saadiq reviewed Petitioner's treatment course at Mayo Clinic, and "discussed the possibility that [Petitioner] might have had a reaction to the flu shot," but noted that "there is no way to conclusively say whether this is related to the flu shot o[r] not." *Id.* However, because Petitioner "had such an extensive reaction that may or may not have been related . . . [she] would recommend [ ] holding off [on] the flu shot at this time," and that they would reevaluate when Petitioner turned sixty-five years old. *Id.*

Petitioner again visited Dr. Rodriguez on September 6, 2018, reporting that "his symptoms of cold intolerance [and] tremor [were] improving," but that he was still not sweating as he had before his prior "flu like episodes." Ex. 3 at 14–15. Dr. Rodriguez opined that it was less likely that a neurological process explained Petitioner's symptoms. *Id.* Rather, his "best hypothesis" was "possible viral or autoimmune insult during the patient's serial episodes of flu-like illness this past fall and winter," but he "was not 100% certain, and there remained an "[u]nclear etiology as to what has caused [Petitioner's] symptoms of cold intolerance and anhidrosis." *Id.* Further testing was not recommended. *Id.* at 16. Later that same month, Dr. Rodriguez advised Petitioner that his "anhidrosis is likely idiopathic given unremarkable [work up] thus far"—explaining "that additional antibody test[s] could be performed, however, [they] were very unlikely to yield any additional information. . ." *Id.* at 8.

On October 19, 2018, Petitioner returned to Dr. Mucha. Ex. 5 at 60. During this visit, Dr. Mucha documented that Petitioner "was recently evaluated [by the] Mayo [C]linic and was found to have decreased sweating or hyperhidrosis [sic] and continues to have cold intolerance," but "[t]he exact etiology cannot be determined, nor did [the] [M]ayo [C]linic provide a[n] etiology." *Id.* He suggested that a "possible cause/hypothesis is that following vaccination, [Petitioner] developed autoantibodies which could have damaged his hypothalamus." *Id.* Dr. Mucha considered medications to help raise Petitioner's body temperature but expressed his concern that such available options had drawbacks to proposed treatments. *Id.*

The filed medical records indicate that Petitioner continued to seek symptomatic care and treatment from various providers at Health Partners throughout 2020. *See generally* Exs. 4 and 5.

II. Hearing Testimony

A. *Fact Witness — William Efron*

Petitioner was the sole fact witness to testify. *See generally* Tr. at 6–21. He briefly recounted the day he received his flu vaccine on October 20, 2017—noting no immediate reaction, but that "a couple days later, [he] started to get flu-like symptoms, [such as] fatigue, body aches, [and] chills." *Id.* at 8, 20. Petitioner communicated with someone on the nurse's line and was told to take over-the-counter medication and to call back if his symptoms did not improve. *Id.* at 8–9. After experiencing several weeks of fluctuating symptoms, Petitioner called back and initiated his overall treatment course with multiple providers. *Id.* at 9.

He then discussed his alleged injuries—anhidrosis, cold intolerance, and fibromyalgia. Petitioner noted that he never experienced an inability to sweat until after his receipt of the flu vaccine—stating further that prior to the flu vaccine, he would sweat normally, whether that was from being in hot weather or partaking in exercise activities. Tr. at 10. Of note, Petitioner testified that he only became aware of his inability to sweat after participating in a TST at Mayo Clinic. *Id.* at 10, 12. As for his cold intolerance, Petitioner recalled that it did not even begin until sometime in mid-2018 (and thus several months post-vaccination). *Id.* at 12. To alleviate these symptoms, Petitioner would frequently take hot showers, sit under a heat lamp, and wear multiple layers of winter attire. *Id.* While Petitioner described some improvement in his cold intolerance, he maintained that he is still "cold all [of] the time." *Id.* Lastly, Petitioner briefly commented on his fibromyalgia—noting that he "did [not] actually know [he] was having symptoms from it" due to his belief that "the cold was so severe" and likely masked its relevant symptoms. *Id.* at 13. He described the symptoms as "his nerves or something under" were hurting all over his body. *Id.*

B. *Petitioner's Experts*

1. Dr. Joseph J. Jeret — Dr. Jeret, a neurologist with expertise in EMG/NCS studies and clinical familiarity with peripheral neuropathies, prepared one written report and testified on behalf of Petitioner. Report, dated June 20, 2023, filed as Ex. 59 (ECF No. 36-1) ("Jeret Rep."). He opined that Petitioner's development of anhidrosis, fibromyalgia, and cold intolerance were collectively caused by his receipt of the flu vaccine on October 20, 2017, given Petitioner's history and the "rather precipitous onset." Tr. at 26; Jeret Rep. at 16.

Dr. Jeret received his undergraduate degree from CUNY Brooklyn College in Brooklyn, New York in 1984, and his medical degree from SUNY Health Science Center at Brooklyn in 1988. *Curriculum Vitae*, filed as Ex. 60 (ECF No. 36-2) ("Jeret CV") at 1. Thereafter, he completed a one-year general internal medicine preliminary year at Maimonides Medical Center, followed by a three-year residency in Neurology and a one-year fellowship in Clinical Neurophysiology at SUNY Downstate. *Id.*; Jeret Rep. at 1; Tr. at 23. He is board certified in Neurology by the American Board of Psychiatry and Neurology and is currently employed by Optum Health Care as an active neurologist and is on staff at two community hospitals—South Nassau Community Hospital and Mercy Medical Center. Jeret CV at 1; Jeret Rep. at 1. Dr. Jeret has published numerous articles in areas related to neurology, reflecting his broad general practice. Jeret CV at 2–7; Jeret Rep. at 1–2.

Dr. Jeret first discussed some of the physiologic factors involved in anhidrosis, and how they pertained to Petitioner's presentation. As he explained, the autonomic nervous system regulates an individual's ability to sweat through a process involving various neurons traveling from the hypothalamus, through the thoracic spine, and to the sweat glands—noting that an absence of sweating will result whenever there is a disruption in this process. Tr. at 27. While he acknowledged that it is often difficult to determine precisely where the disruption may occur along the pathway, it could be a functional rather than structural problem—especially here, given the absence of evidence (MRI results) suggesting a stroke or tumor in the hypothalamus. *Id.* at 28. This had in fact led Petitioner's treating physicians to consider antibodies related to the flu vaccine as possibly attacking the hypothalamus. *Id.* at 36; Ex. 4 at 62–63 (indicating "damage was in dorsal columns").

Dr. Jeret gave considerable weight to the post-vaccination onset of Petitioner's symptoms in opining that the two were linked. He maintained that Petitioner begin exhibiting some initial symptoms (even if somewhat nonspecific in nature) three to four days post-vaccination—a timeframe he deemed consistent with an autoimmune reaction, as commonly documented in cases of Guillain-Barré syndrome ("GBS") following receipt of the flu vaccine. Tr. at 38, 46; Jeret Rep. at 14. Moreover, Dr. Jeret pointed to Petitioner's medical records—which demonstrated an onset of three to four days post-vaccination rather than an immediate onset—and further emphasized the

likelihood of an autoimmune etiology. Tr. at 39. There was, he proposed, nothing else in the record other than the vaccine that might explain Petitioner's symptoms. *Id.* at 36. And it was possible Petitioner's anhidrosis began to manifest well before the spring of 2018, even if Petitioner himself did not so realize. *Id.* at 46-47. Dr. Jeret did not completely explain in his testimony, however, how or why these initial, malaise-like post-vaccination symptoms related to Petitioner' months-later manifestations of anhidrosis-like symptoms. And Dr. Jeret could not provide an overarching explanation of how the purported fibromyalgia and anhidrosis related, *i.e.*, which began first, or how the two developed concurrently in the wake of vaccination. *Id.* at 47–48.

Dr. Jeret also spent some time discussing fibromyalgia in general, in an effort to connect it with Petitioner's other issues. Tr. at 28–35. To obtain a formal diagnosis of fibromyalgia, practitioners utilize criteria set forth by the American College of Rheumatology in 1990. *Id.*; Jeret Rep. at 11–12 (citing F. Wolfe et al., *The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee*, 33 Arthritis Rheum 160 (1990), filed as Ex. 70 (ECF No. 37-10)). Those criteria include "[nineteen] different areas where the clinician had to press with a certain amount of pressure" and "[i]f eleven out of [nineteen] [areas] where sufficiently tender, then that person officially qualified for the diagnosis of fibromyalgia. Tr. at 29. In clinical practice, however, there is variability among clinicians when defining what formally satisfies the diagnostic criteria—leading to their broad application. *Id.* In addition, Dr. Jeret noted, those criteria were later modified to "allow 'use in epidemiologic and clinical studies without the requirement for a tender point examination,'" and thus they have more utility for formal studies than for purposes of clinical diagnosis. *Id.* at 30; Jeret Rep. at 13.

Mr. Efron, Dr. Jeret opined, "may or may not have satisfied the [strict] criteria" for fibromyalgia. Tr. at 34–35. But Dr. Jeret nevertheless deemed that diagnosis proper given the record, with some evidence of it beginning a month post-vaccination. Tr. at 32. Dr. Jeret later admitted, however, that the Mayo Clinic *itself* had not deemed Petitioner to be properly so diagnosed. *Id.* at 44.

2. Omid Akbari, Ph.D. — Dr. Akbari prepared three written reports and testified on behalf of Petitioner. Report, dated June 24, 2022, filed as Ex. 11 (ECF No. 28-1) ("Akbari First Rep."); Report, dated May 1, 2024, filed as Ex. 77 (ECF No. 52-1) ("Akbari Supp. Rep."); Report, dated Aug. 3, 2024, filed as Ex. 110 (ECF No. 70-1) ("Akbari Second Supp. Rep.").

Dr. Akbari is a professor of allergy and immunology of Keck School of Medicine at the University of Southern California. *Curriculum Vitae*, filed as Ex. 12 (ECF No. 28-2) ("Akbari CV") at 1. He received his Bachelor's and Master's Degrees from University College London in 1993 and 1995, respectively. *Id.* Thereafter, he received his Ph.D. in Cellular and Molecular Immunology from the National Institute for Medical Research in London before completing a

post-doctoral fellowship at Stanford University. *Id.* Dr. Akbari has and continues to serve on the editorial board of several journals, and he has numerous publications focused on the area of immunology and allergy research. *Id.* at Akbari First Rep. at 2. He also has particular experience on the subjects of "immune tolerance and how immune cells induce autoimmune and allergic diseases." Akbari First Rep. at 2. Dr. Akbari is not a medical doctor, however, and therefore he does not diagnose or treat patients with neurological diseases in a clinical setting.

Dr. Akbari generally opined that Petitioner's receipt of the flu vaccine on October 20, 2017, induced the inflammasome "followed by the molecular mimicry, [which] caused hypothalamus inflammation, [causing] anhidrosis in [Petitioner]." Tr. at 173. He characterized the inflammasome[9] to be "the start of the immune system," and noted that it can be stimulated by vaccines as well as "any type of infection, [or] any type of danger that gets into any biological system." *Id.* at 174–75, 214. Without some initial inflammasome reaction, a subsequent adaptive response (at which time the immune system "learns" to react to a specific infectious antigen or vaccine component) will not also occur. *Id.* at 194.

Thereafter, an inflammatory process begins, and regulatory T cells are then responsible for containing the inflammation or employing a new response to combat the unwanted immune response. Tr. at 176. But an individual can have an abnormal T cell response, featuring "too much [of] [a] suppressor effect," or where the T cells "cannot really exert their suppressive function," leading to "massive inflammation or inflammation at certain sites." *Id.* at 200–01. Inflammasome reaction also results in stimulation of "T helper cells" responsible for encouraging release of other cytokines and aiding in the B cell process resulting in the creation of antibodies. *Id.* at 195. Activation of the inflammasome, Dr. Akbari contended, will be reflected by the post-vaccination malaise an individual (like Petitioner) often feels, characterized by congestion, fluctuation in temperature, as well as flu-like symptoms. *Id.* at 177, 178. If the regulatory immune cells do not control the process, significant damaging inflammation becomes possible. *Id.* at 180.

Vaccines, Dr. Akbari maintained, could trigger a pathologic process resulting in the kind of autoimmune injury that he proposed Petitioner experienced. A vaccine cannot work without inducing an inflammasome reaction, he maintained—and when a vaccine's components are incapable by themselves of providing the necessary stimulation, the vaccine formulation requires adjuvants or conjugates to do so. Tr. at 174, 180.[10] Dr. Akbari offered several items of medical

[9] "The inflammasome is "a complex of cryopyrin, caspase-1, and other proteins, found in phagocytic cells and related to the body's system of innate immunity. Assembly of the inflammasome leads to activation of caspase-1 and resultant cleavage and activation of interleukins IL-1ß and IL 18 in the inflammatory response." *Inflammasome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25203&searchterm=inflammasome (last visited Jan. 2, 2025).

[10] Dr. Akbari contended as well that even though the form of the flu vaccine at issue is not adjuvanted, its antigenic components alone were sufficient to stimulate the inflammasome. Tr. at 213.

literature to support this contention. *Id.* at 181; L. Christian et al., *Proinflammatory Cytokine Responses Correspond with Subjective Side Effects after Influenza Virus Vaccination*, 26 Vaccine 3360 (2015), filed as Ex. 80 (ECF No. 52-4); S. Crooke et al., *Inflammasome Activity in Response to Influenza Vaccination is Maintained in Monocyte-Derived Peripheral Blood Macrophages in Older Adults*, 2 Frontiers Aging 1 (2021), filed as Ex. 79 (ECF No. 52-3) ("Crooke"); S. Fourati et al., *Pan-Vaccine Analysis Reveals Innate Immune Endotypes Predictive of Antibody Responses to Vaccination*, 23 Nature Immunology 1777 (2022), filed as Ex. 84 (ECF No. 52-8).

(On cross, however, Dr. Akbari was confronted with the fact that some of this literature was not on all points with his contention that the flu vaccine was likely to stimulate the inflammasome enough to set off an aberrant immune process. One article, for example, involved an in *vitro* study of the stimulative impact of certain live infections on the inflammasome, rather than an inactivated virus like the flu vaccine's antigenic components. Tr. at 214; R. Tweedell et al., *A Comprehensive Guide to Studying Inflammasome Activation and Cell Death,* 15 Nat. Protocols 3284, 3285-86 (2020), filed as Ex. 112 (ECF No. 71-2). In Crooke, a strong, adjuvant-like experimental "agonist"[11] (not something that would ever be comparable to the contents of any inactivated flu vaccine) was utilized in order to derive experimentally-observable results in serum testing of samples taken from vaccinated individuals. Crooke at 4. And other literature established that the flu vaccine itself was not all that immune-stimulative. *See, e.g.*, W. Tang et al., *Post-Vaccination Serum Cytokines Levels Correlate with Breakthrough Influenza Infections,* 13 Sci. Rep. 1174, 1177 (2023), filed as Ex. 81 (ECF No. 52-5).

Dr. Akbari further maintained that it was possible to measure the inflammasome reaction to vaccination, although he allowed that there were significant biological challenges in doing so, especially since its reaction would be rapid in the wake of vaccination, waning not long thereafter. Tr. at 186. In particular, inflammasome reactions could be ascertained by looking to evidence of post-vaccination, localized inflammation, along with cytokine levels (and whether they increased after vaccination), since it was understood that vaccination leads to upregulation of proinflammatory cytokines. *Id.* at 183–84, 185–86. In addition, individual susceptibility to vaccination or infection can also make studying adverse effects of vaccines challenging. *Id.* at 189.

Dr. Akbari also expanded on the putative connection between initial, vaccine-caused inflammasome activation and a subsequent pathologic process. Tr. at 195–96. He opined that robust stimulation of the inflammasome is associated with high levels of a particular kind of T helper cell (Th17 cells), and that these in turn can play roles in both central and peripheral nervous system pathogenic neuroinflammatory processes. *Id.* at 197. These T helper cells were in fact

[11] An agonist is a chemical or drug that binds to a receptor on or inside a cell, causing a biological response. *Agonist*, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/agonist (last visited Jan. 2, 2025). In experiments, agonists are employed to evaluate a receptor reaction.

capable of penetrating the blood brain barrier[12] ("BBB") and reaching the central nervous system due to specific trafficking markers they possess. *Id.* When any aspect of the nervous system is involved, the "immunoregulatory pathways" are significantly reduced, and thus other kinds of T cells have a harder time combating the inflammation. *Id.* at 201. (On cross, however, Dr. Akbari was confronted with the fact that he had not identified evidence specifically establishing a likely relationship between the flu vaccine and the induction of a T-helper cell pathogenic response. Tr. at 222).

Mr. Efron, Dr. Akbari argued, had likely experienced a high inflammasome response following his receipt of the flu vaccine on October 20, 2017, as evidenced by his subsequent development of flu-like symptoms and fluctuation in temperature. Tr. at 207. In response, it was likely that Petitioner's T regulatory cell function was significantly reduced, and therefore failed to adequately suppress the immune response. *Id.* at 200, 207. It did not matter, Dr. Akbari maintained, that Petitioner had received the flu vaccine in the past without experiencing a comparable reaction, since the vaccine's formulation (and its specific antigenic contents) varied year to year. *Id.* at 198–99.

Dr. Akbari further attempted to link this initial proinflammatory process to the anhidrosis with which Petitioner was diagnosed (albeit many months after vaccination). He argued, for example, that anhidrosis itself had been linked to a T helper cell-driven process. Tr. at 203; R. Kageyama et al., *Acquired Idiopathic Generalized Anhidrosis (AIGA) and Its Complications: Implications for AIGA as an Autoimmune Disease,* 22:8489 Int. J. Mol. Sci. 1, 9 (2021), filed as Ex. A Tab 3 (ECF No. 31-4). (Significantly, however, and as explained later by Respondent's expert Dr. Donofrio, Petitioner was never diagnosed with acquired idiopathic generalized anhidrosis ("AIGA")—and the record would not support that diagnosis in any event).

Moreover, the same pro-inflammatory process initiated by vaccination might later also result in sufficient BBB interference for pathogenic immune cells to cross into the central nervous system, where they could interfere with brain components relevant to sweating. The hypothalamus, unlike other parts of the central nervous system, has a very "thin-line" barrier, meaning it is not fully protected. Tr. at 196. It was therefore the likely situs of vaccine-driven damage. Tr. at 224. Such an attack on Petitioner's hypothalamus "probably started by hypohidrosis[13] first for the first

[12] The blood-brain barrier is defined as "the barrier system separating the blood from the parenchyma of the central nervous system. Its anatomic component consists of unique endothelial cells in the brain capillaries, having tight junctions without fenestrations and with few microvilli and few vesicles for fluid transport. Its physiologic component in part consists of enzymes unique to the brain endothelia and of active transport via carrier proteins." *Blood-brain Barrier*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60232 (last visited Jan. 2, 2025).

[13] In hypohidrosis, an individual experiences diminished sweating in response to a stimulus. *Hypohidrosis*, Dorland's Medical Dictionary Online,

few days[,] or for a while [before] becom[ing] anhidrosis, which is a severe form." Tr. at 208. But Dr. Akbari admitted that he could not point to any evidence in the record to establish the existence of hypohidrosis but maintained that a process progressing to anhidrosis would unfold over time due to chronic inflammation. *Id.* at 209.

Respondent noted other deficiencies with this aspect of Dr. Akbari's causation theory. For example, Dr. Akbari essentially proposed that a putative hypothalamus attack reflected an autoimmune process, but he could not (and had not) identify any homologic/sequential or structural identity between components of the flu vaccine and the hypothalamus—although he maintained in response that it was not critical to the success of his theory that he do so in the first place. Tr. at 225, 228–29. (In fact, Dr. Akbari argued that a cross reactive process mediated by autoimmunity did not require perfect homology. Tr. at 257). He also at times seemed to embrace a process that was less antibody-driven than "cell-mediated"—meaning attributable to T cells (which are far less likely to be created due to vaccination). *Id.* at 225–26.[14]

Other record evidence was supportive of the causation theory, Dr. Akbari maintained. For example, several treating physicians had associated Petitioner's development of anhidrosis to inflammation of the hypothalamus. Tr. at 198. And he contended the timeframe for onset was medically acceptable. The initial inflammasome stimulation was evidenced by Petitioner's close-in-time flu-like symptoms—and then, as the process evolved (first due to immune dysregulation), Petitioner was eventually diagnosed with anhidrosis. *Id.* at 206–09. The fact that he lived in a cold region of the U.S. likely masked his symptoms somewhat. *Id.* at 208. At the same time, Dr. Akbari could identify no imaging evidence of hypothalamus damage experienced by Petitioner, although he claimed in response that the hypothalamus was too small a structure to pick up on MRI (and also stressed that treaters had nevertheless speculated that this was a potential source of Petitioner's anhidrosis). *Id.* at 226, 230.

C. *Respondent's Experts*

1. Dr. Peter Donofrio — Dr. Donofrio, a neurologist, prepared one written report and testified on behalf of Respondent. Report, dated Sept. 16, 2022, filed as Ex. A (ECF No. 31-1) ("Donofrio Rep."). Dr. Donofrio opined that Petitioner's receipt of the flu vaccine did not cause his subsequent development of anhidrosis or fibromyalgia (and he did not deem the latter diagnosis to have sufficient evidentiary support in any event). Tr. at 54.

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https://www.dorlandsonline.com/dorland/definition?id=24259&searchterm=hypohidrosis (last visited Jan. 2, 2025). It is thus distinguishable from the *total inability* to sweat—anhidrosis.

[14] *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 332044, at *55 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (explaining difference between humoral and cell-mediated arms of immune response); *see also* Flucelvax Quadrivalent Package Insert, filed as Ex. J (ECF No. 53-7) ("Flucelvax Package Insert") at 13 (discussing how the vaccine's mechanism results in production of antibodies against anticipated strains of wild flu virus for a given influenza season).

Dr. Donofrio is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular medicine. *Curriculum Vitae*, filed as Ex. B (ECF No. 31-7) ("Donofrio CV") at 2. After receiving his medical degree from Ohio State University School of Medicine, he completed residencies in internal medicine and neurology, as well as completed a neuromuscular fellowship. *Id.*; Donofrio Rep. at 1. Throughout his career, Dr. Donofrio held various academic appointments at Vanderbilt University School of Medicine, Wake Forest University School of Medicine, and University of Michigan Medical Center. Donofrio CV at 2–3; Tr. at 52. He later retired from the practice of neurology in July 2021. Tr. at 51. Dr. Donofrio has experience in evaluating and caring for patients suffering from a spectrum of neuropathies, including GBS, as well as muscle disorders and motor neuron diseases. Donofrio Rep. at 1. Much of his published work is focused on the field of peripheral nerve diseases and peripheral neuropathy. Tr. at 52; Donofrio CV at 13–32.

Dr. Donofrio defined fibromyalgia to be "a poorly described condition of diffuse body pain, often associated with tenderness in regions in the back of the neck, [and] the upper thoracic and lower thoracic region[s]." Tr. at 55. But the record herein did not support such a diagnosis. Petitioner had received a thorough evaluation at the Fibromyalgia and Chronic Pain Clinic at Mayo Clinic, but was not found to meet the criteria for such a diagnosis. *Id.* Although Petitioner offered several items of medical literature to further bulwark his argument that his receipt of the flu vaccine caused his subsequent development of his alleged injuries, Dr. Donofrio criticizes many of these references—noting their failure to either discuss the flu vaccine in its entirety, or to even establish a meaningful relationship between the flu vaccine and fibromyalgia. *Id.* at 57–59; *see also* J. Ablin et al., *Fibromyalgia, Infection and Vaccination: Two more Parts in the Etiological Puzzle*, 27 J. Autoimmunity 145 (2006), filed as Ex. 61 (ECF No. 37-1); D. Buskila et al., *Etiology of Fibromyalgia: The Possible Role of Infection and Vaccination*, 8 Autoimmunity Rev. 41 (2008), filed as Ex. 62 (ECF No. 37-2); A. Goebel et al., *Passive Transfer of Fibromyalgia Symptoms from Patients to Mice*, 131 J. Clinical Investigation 1 (2021), filed as Ex. 64 (ECF No. 37-4). (Dr. Donofrio did also admit that fibromyalgia was a subject outside his immediate expertise. Tr. at 77).

By contrast, Dr. Donofrio agreed that Petitioner's anhidrosis had been confirmed by the thermoregulatory testing done at the Mayo Clinic. Tr. at 60–62, 82, and 84. But Petitioner could not be deemed to have experienced AIGA. *Id.* at 60. Symptoms of AIGA oftentimes include "heat intolerance, propensity to heat stroke, fever, [or] inability to be exposed to hot weather or humidity." *Id.* The record in Dr. Donofrio's view did not support this particular diagnosis. For example, Petitioner testified to using a heat lamp to help with his cold intolerance—something that "would be relatively contraindicated in anhidrosis for the fear it would make symptoms worse." *Id.* The same was true of Petitioner's exercise routine, which would cause him to generate body heat and eventually develop a fever and other symptoms commonly associated with anhidrosis. *Id.*

Dr. Donofrio did not accept the contention that anhidrosis could be vaccine-caused. He disputed analogizing it to known autoimmune-mediated demyelinating conditions, like GBS or multiple sclerosis, noting their distinctive natures even if GBS sometimes itself had some "autonomic involvement." *Id.* at 70. He also noted that an individual who developed anhidrosis via an autoimmune mechanism would likely exhibit certain abnormal antibody levels, such as acetylcholine receptor ganglionic neuronal antibody ("AChR"), yet in this case "[n]o informative autoantibodies were detected," including AChR. *Id.* at 121; Ex. 3 at 121 (paraneoplastic autoantibody evaluation on July 27, 2018, yielded unremarkable results); Donofrio Rep. at 5. And he had been unable to find any publications, including case reports,[15] supporting the concept that the flu vaccine can cause anhidrosis. *Id.*

Rather than the flu vaccine, Dr. Donofrio opined, the most likely cause for Petitioner's condition was an "anatomical abnormality in the cervical spine," because that is the "most prominent mechanism[] for explaining [Petitioner's] anhidrosis in the setting of normal autonomic testing at the Mayo Clinic." Tr. at 72, 73. Petitioner likely suffered from this abnormality for years prior to his receipt of the flu vaccine. *Id.* at 68. In addition, the records from Dr. Bennaroch's treatment of Petitioner in July 2018 pointed away from a vaccine-associated etiology. *Id.* at 62. Under the "impression" section, Dr. Benarroch had listed two etiologic possibilities to explain Petitioner's presentation—cervical myelopathy and anhidrosis—but had then gone on to state that anhidrosis alone could not be explanatory, because "[t]he association between the lack of sweating in the thermoregulatory sweat test and a normal sweating in the autonomic reflex screen suggests a potential central cause or longstanding reduction of sweat gland activity as can be seen in essential anhidrosis." Ex. 3 at 133.

Dr. Donofrio also doubted that a medically acceptable temporal relationship existed between Petitioner's October 2017 vaccination and later first demonstrated manifestations of anhidrosis. Petitioner testified to noticing anhidrosis symptoms only after he underwent the TST at the Mayo Clinic in July 2018—thus from a "laboratory standpoint, that might be the onset." Tr. at 67. And in Dr. Donofrio's view, Petitioner did not exhibit many of the "classic symptoms" for anhidrosis any sooner, although it was difficult based on the record in this case to pinpoint a likely onset date. *Id.*

2. John Bates, Ph.D. — Dr. Bates testified on Respondent's behalf, attempting to identify the immunologic deficiencies in Petitioner's causation theory.[16] Dr. Bates ultimately

[15] Dr. Donofrio also briefly commented on case reports in general as constituting a poor form of causation evidence. Case reports typically review medical events involving an individual developing a particular condition which may relate temporally to something else, like a prior vaccination. Here, a case report would look to describe an individual who received a flu vaccine and developed anhidrosis thereafter—but Dr. Donofrio could not even find *one* such report in which post-vaccination anhidrosis was observed. Tr. at 69.

[16] Dr. Bates did not prepare a written report in this case. He was identified by Respondent as an expert witness only in reaction to Petitioner's somewhat-late filing of Dr. Akbari's supplemental report in early May of this year. But

opined that the flu vaccine Petitioner received could not have caused his fibromyalgia or anhidrosis. Tr. at 90.

Dr. Bates received his undergraduate degree in Biochemistry from Mississippi State University in 1998, and his Ph.D. in Microbiology from the University of Alabama at Birmingham in 2005. *Curriculum Vitae*, filed as Ex. C (ECF No. 47-1) ("Bates CV") at 1; Tr. at 85. Thereafter, he completed a post-doctoral fellowship in the Department of Microbiology and Immunology at Wake Forest University School of Medicine, followed by another post-doctoral fellowship in the Vaccine Center at Vanderbilt University School of Medicine. *Id.* Throughout his career Dr. Bates has held multiple academic appointments, and currently serves as an Associate Professor in the Department of Cell and Molecular Biology at the University of Mississippi Medical Center ("UMMC"). *Id.* at 2; Tr. at 86. He also serves as the Scientific Director of the Human Immunology and Inflammation Biomarker Core Laboratory at UMMC. *Id.* Dr. Bates has published approximately thirty papers—a majority of which focus on vaccines and immunology. Bates CV at 3–5; Tr. at 88. Like Dr. Akbari, Dr. Bates's expertise does not extend to medical diagnostic matters.

Dr. Bates initially focused on the nature of the vaccine in question. Petitioner received a quadrivalent flu vaccine, which "contains [a] virus that has been recovered from cell culture" and contains approximately fifteen micrograms of HA antigen—one of the main antigens of influenza—plus other significant components of influenza, but *not* an adjuvant. Tr. at 90; Flucelvax Package Insert at 12. The viral particles contained in this version of the vaccine are inactivated, and "an inactivated vaccine does not . . . operate through the same immune stimulating pathways as a live vaccine or infection." *Id.* at 91.

As a general matter, Dr. Bates argued, there was scant support for the proposition that the flu vaccine might be associated with anhidrosis.[17] Most of the case reports cited by Petitioner's experts allegedly demonstrating a vaccine relationship were facially inapposite—involving, for example, distinguishable vaccines. Tr. at 116–21; H. Kwon et al., *Recurrent Generalized Anhidrosis following COVID-19 Vaccinations*, 67 Muscle & Nerve e12 (2022), filed as Ex. 76 (ECF No. 43-3) (reporting a case of two events of acquired generalized anhidrosis following receipt of two COVID-19 vaccines); C. Hsieh & T. Tsai, *Acquired Idiopathic Generalized Anhidrosis Diagnosed following mRNA COVID-19 Vaccination—A Case Series*, 64 Aus. J. Dermatology e76 (2023), filed as Ex. 75 (ECF No. 43-2) (discussing five cases of anhidrosis

Respondent did file a Notice of Testimony detailing the anticipated subject-matter of Dr. Bates's trial testimony. *See* Notice, dated May 16, 2024 (ECF No. 55).

[17] Dr. Bates also briefly responded to Dr. Jeret's offering of case reports to support the notion that fibromyalgia can occur post-vaccination. Tr. at 127. But because (as noted below) I do not find the alleged injury of fibromyalgia to be evidentiarily supported by the medical records filed in this case, there is no need for extended consideration of these arguments.

following receipt of COVID vaccines). And there are significant differences between the impact of a live viral *infection* and an inactivated vaccine like the version of the flu vaccine Petitioner received—meaning a case report involving such a live virus was unhelpful as well, even if both involved influenza to some degree. Tr. at 122; P. Ghosh et al., *Generalized Anhidrosis in a Child following Presumptive H1N1 Influenza*, 22 Clin Auton Res 109 (2012), filed as Ex. 74 (ECF No. 43-1).

The fact that Petitioner received an inactivated vaccine was, to Dr. Bates, an important reason for doubting a vaccine association. This kind of vaccine was not likely to perform the function proposed in Dr. Akbari's theory, activating the inflammasome and then causing the "production of cytokines [which] mediate[d] the subsequent [immune] dysregulation." Tr. at 93, 94, 102–03. In support, he referenced literature considering the comparative ability of live versus inactivated viruses in stimulating the inflammasome. T. Ichinohe et al., *Inflammasome Recognition of Influenza Virus is Essential for Adaptive Immune Responses*, 206 J. Experimental Med. 79 (2006), filed as Ex. L (ECF No. 53-9) ("Ichinohe").

Ichinohe noted that the risk of a live influenza viral infection was considerable, and therefore "there is an urgent and important public health need to develop effective vaccines" in response. Ichinohe at 79. To that end, the study sought to evaluate the role of the inflammasome in assisting in "the initiation of adaptive immunity after physiological infection with the influenza virus." *Id.* at 80. Ichinohe's authors found that only the live virus was likely to activate the inflammasome (in comparison to a UV-light-inactivated version). Ichinohe at 80, 88, Fig. S1.[18] Based on their findings, Ichinohe's authors proposed that "an ideal adjuvant candidate" for inclusion in flu vaccines would be components sufficient to stimulate the inflammasome during, or as a feature of, its adaptive immune response activity. *Id.* at 85. Thus, implicit to Ichinohe's findings is the assumption that the *existing* form of vaccine is less helpful in stimulating the inflammasome, at least in the context of the adaptive response (which is the goal of virtually any vaccine: to teach the body to mount a response to a pathogen in the future).

Dr. Bates deemed literature offered by Dr. Akbari on the vaccine's ability to stimulate the inflammasome to be less persuasive. Thus, even though Crooke showed some level of cytokine stimulation by the inflammasome after receipt of an H1N1 influenza vaccine (Crooke at 4), the identified levels of cytokine production were not, in Dr. Bates's opinion, sufficiently "biologically appreciable" to be medically significant. Tr. at 95. Other items of literature offered to support Dr.

[18] Dr. Akbari later argued that Ichinohe was distinguishable because the UV-purified form of flu virus it employed in its study was not congruent with the version of vaccine at issue in this case, which involved inactivating its viral components in a different manner. *See* Tr. at 258. But I give this contention relatively low weight. Ichinohe still supports Respondent's argument that it would take *more* than any inactivated form of flu virus used in a vaccine—however inactivated—to stimulate the inflammasome to the degree posited by Dr. Akbari's theory, in comparison to what a wild virus can accomplish. Indeed, the point of Ichinohe was to try to identify how to render a flu vaccine *better* at promoting adaptive immunity. Ichinohe at 85.

Akbari's opinion did not discuss the vaccine at issue, establish what levels of cytokines would more likely be pathogenic, or even speak to inflammasome activation resulting in the alleged injuries. *See generally Id*. at 95–102; N. Chatziandreuo et al., *Macrophage Death following Influenza Vaccination Initiates the Inflammatory Response that Promotes dendritic Cell Function in the Draining Lymph Node*, 18 Cell Reports 2427, 2427 (2017), filed as Ex. 78 (ECF No. 52-2) (concluding that "[t]he mechanism by which inflammation influences the antibody response to vaccines is unclear").

Dr. Akbari's contentions about the role of Th17 helper cells was also criticized by Dr. Bates. Tr. at 104. Dr. Bates agreed that certain cytokines attributable to inflammasome activation might impact subsequent T helper 17 cell differentiation, but maintained that he was unable to find any data to demonstrate Th17 involvement in the development of the injury discussed in Dr. Akbari's supplemental report (small fiber neuropathy—not something Petitioner alleges to have experienced). *Id*. at 104–05. Dr. Akbari was thus emphasizing an immune cell disease role that could not be linked to vaccination in the first place.

It was especially unlikely that the October 2017 vaccination would have triggered a response never before experienced by Petitioner, Dr. Bates reasoned, given Petitioner's history of having received the flu vaccine multiple times in the past without incident. Tr. at 106. And the article offered by Dr. Akbari to address this contention did not support the argument. *See* N. Rout et al., *Impaired IL-17 and Cytotolytic Responses to Influenza Vaccine Antigens in Aging Nonhuman Primates*, 210 J. Immunol 1 (2023), filed as Ex. 108 (ECF No. 66-1) ("Rout"). The filed version of Rout was merely an abstract pulled from a poster presented at a conference, rather than the whole article. Tr. at 108–09; Rout at 1. Moreover, Rout appeared only to have investigated "early cellular responses to re-exposure with seasonal flu vaccine antigens in a cohort of pre-vaccinated young and old rhesus macaques (*i.e.* non-human primates), finding that "older macaques showed significantly impaired IL-17[19] production and CD107a upregulation in response to vaccine antigens." Rout at 1. In Dr. Bates's view, the weaker IL-17 response demonstrated in Rout went against Dr. Akbari's proposed theory, since it suggested a *less* robust vaccination response was likely after multiple exposures—not a more severe response. Tr. at 109–10.

Dr. Bates offered supplemental testimony after Dr. Akbari expanded on his theory that the vaccine-induced pathogenic process had resulted in damage to Petitioner's hypothalamus.[20] He

[19] "Interleukin-17" is known as "a key cytokine that links T cell activation to neutrophil mobilization and activation" that "can mediate protective innate immunity to pathogens or contribute to the pathogenesis of inflammatory diseases." *Basic Biology and Role of Interleukin-17 in Immunity and Inflammation*, National Library of Medicine, https://pmc.ncbi.nlm.nih.gov/articles/PMC4530463/ (last visited Jan. 2, 2025).

[20] Dr. Akbari had only included this part of his opinion in a late-filed report that was added to the record before the first hearing date (which had been intended to be the *sole* hearing date—but which Dr. Akbari had been unable to attend). *See* Petitioner's Witness List and Glossary of Terms, dated May 7, 2024 (ECF No. 51) at n.1. Thus, when Dr.

contended that there was no evidence in this case that Petitioner had in fact experienced hypothalamus inflammation (reiterating his prior arguments that the version of the flu vaccine could not have sufficiently stimulated the inflammasome to even initiate such a process). Tr. at 235–36, 238 (MRI evidence did not confirm this contention). He also noted that Petitioner had offered insufficient evidence to show how molecular mimicry involving the hypothalamus would lead to a damaging cross-reaction. *Id.* at 243. Overall, the theory was too general, and did not include medical or scientific literature specific to the alleged injury. *Id.* at 236–37, 239.

Dr. Bates further referenced the medical records offered herein to underscore his views on the lack of evidentiary support for a vaccine reaction. They documented multiple visits by Petitioner to allergists and immunologists, as well as other specialists, yet none of these treaters had diagnosed Petitioner with an autoimmune disease. Tr. at 114. And Dr. Bates expressed doubt that the timing of Petitioner's onset could be reasonably associated with his October 2017 vaccination. Indeed, he proposed it was unclear when Petitioner was alleging onset to have occurred; while Petitioner had testified that he did not became aware of his anhidrosis until after he underwent TST at the Mayo Clinic (which was approximately nine months post-vaccination), Dr. Jeret had argued that symptoms began three to four days after vaccination, while Dr. Akbari's relied on case reports involving a distinguishable injury (small fiber neuropathy) following vaccination approximately nine days later. Tr. at 132; J. Kafaie et al., *Small Fiber Neuropathy following Vaccination*, 18 J. Clinical Neuromuscular Disease 37 (2016), filed as Ex. 95 (ECF No. 52-19).

III. Procedural History

The matter was initiated in the fall of 2020. After it was activated out of "pre-assignment review" almost a year later, the parties began the process of obtaining expert opinions and filing reports in the matter, beginning with Dr. Akbari's report in June 2022. While this process was underway, Respondent filed his Rule 4(c) Report opposing entitlement. ECF No. 32. Expert discovery was not completed until August 2023, and I thereafter set a prehearing schedule. The matter was tried on non-consecutive dates in June and August 2024, to accommodate expert schedules. No post-trial briefs were filed, and the claim is ripe for resolution.

IV. Relevant Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—

Akbari's live testimony was finally obtained in August 2024, Respondent re-called Dr. Bates to address this aspect of the Petitioner's causation theory.

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[21] Petitioner can only advance a causation-in-fact claim, since the injuries of fibromyalgia and anhidrosis are not included in the Table.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

[21] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" with respect to the first *Althen* prong deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir.

1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less

deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are

employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir.

2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

At the outset, and as I stated at trial (after hearing testimony from Petitioner and Dr. Jeret (Petitioner's treatment-oriented expert)), I find that the alleged injury of fibromyalgia has *not* been preponderantly established. Tr. at 162–63. Petitioner was specifically evaluated at the Mayo Clinic for fibromyalgia in a comprehensive manner—but the diagnosis was not embraced.[22] Ex. 3 at 91–92; 97–98. And no other record evidence preponderantly supports the diagnosis. While it may be the case that the formal diagnostic criteria for fibromyalgia (which were primarily generated for purposes of research studies) should not be rigidly applied in a clinical setting, the record nevertheless does not support the diagnosis based on the evidence before me. Thus, Petitioner has failed to demonstrate the presence of this injury—meaning it cannot be the basis for a vaccine injury claim. *Broekelschen*, 618 F.3d at 1350.

By contrast, testing confirmed the existence of Petitioner's anhidrosis[23] (at least as of mid-2018), and this finding is uncontested. Ex. 3 at 133–35, 155, 182. As some of the literature filed in this case indicates, anhidrosis "is characterized by a lack of sweating or reduced sweating (hypohidrosis) in conditions that would normally promote sweating, such as exercise, high temperature or excessive humidity." T. Munetsugu et al., *Revised Guideline for the Diagnosis and Treatment of Acquired Idiopathic Generalized Anhidrosis in Japan*, 44 J. Dermatology, 394, 396 (2017), filed as Ex. 66 (ECF No. 37-6) (The record is not, however, supportive of an AIGA diagnosis, for the reasons offered by Dr. Donofrio. Accordingly, the fact that AIGA *may* be thought to be autoimmune in character cannot be relied upon to explain Petitioner's anhidrosis).

Accordingly, my analysis focuses only on anhidrosis as a putative vaccine injury. But Petitioner has not carried his burden of proof of establishing any of the three *Althen* prongs with sufficient preponderant evidence.

First, it has not been shown that the flu vaccine likely "can cause" anhidrosis. Dr. Akbari's causation theory was unreliable, and has not been bulwarked with sufficient evidence. In effect, he seeks to do what so many other unsuccessful claimants attempt: describe ways in which

[22] Although Dr. Donofrio also proposed that a fibromyalgia diagnosis lacks substantiation, he admitted the subject falls more within the expertise of a rheumatologist—and hence I do not give his opinion on this topic significant weight. Of course, Dr. Jeret (like Dr. Donofrio) is a neurologist as well, rather than a rheumatologist—so there is no reason to favor Dr. Jeret's view of this topic either.

[23] I differentiate this from a diagnosis of AIHA, which Dr. Donofrio credibly explained is not supported by the record. But Dr. Donofrio did not contest that the TST confirmed anhidrosis, and it stands as a medical condition that can manifest for a number of reasons; its presence is not dependent on an AHIA diagnosis.

vaccines impact the immune system, and then convert that into a story of an aberrant process, but without the kind of specific support needed to find it likely could occur. Dr. Akbari's theory also has a poorly-substantiated, globally-overarching character, in which the initial event of vaccination manages to wreak havoc at *every step of the immune process*, from the innate production of cytokines when the vaccine is first administered, to the immune system's self-regulating safeguards, to the adaptive system's targeted response to the vaccine's antigens. Such a theory is too sweeping to be deemed preponderantly-established.

Respondent highlighted many deficiencies with Petitioner's causation theory. For example, even if an inflammasome reaction is important to an initial immune response, it has not been shown that the flu vaccine (which is inactivated and lacks an adjuvant) would so robustly stimulate the inflammasome that an aberrant "chain reaction" would begin with vaccination. It was not demonstrated, furthermore, that the cytokine upregulation process that vaccines are known to trigger will necessarily result in production of *enough* cytokines, and of the right type, to create a harmful inflammatory milieu (even if those cytokines can still produce some level of personal malaise in individuals receiving the vaccine).

Moving on, it also has not been preponderantly shown how this immune process, if initiated by vaccination, would then become chronic or pathologic, evolving from a systemic reaction to a focal attack on the hypothalamus, penetrating the BBB "wall" in the process in order to reach the brain. Dr. Akbari's contentions about regulatory cell dysfunction were inadequately linked to evidence that a vaccine could cause such dysfunction. It was not established that any increase in T helper cells attributable to receipt of the flu vaccine will go on to be pathologic. Nor was it persuasively demonstrated how or why the initial innate response to vaccination would evolve into an adaptive attack on the brain structures associated with anhidrosis. Rather, these causal components are *assumed* to be demonstrated, based on generalities about the immune system and the role different immune cells play in various known disease processes only faintly analogous to anhidrosis. Indeed, even though vaccines seek *primarily* to cause the body to generate antibodies to a vaccine's antigens, Dr. Akbari did not show how a process he seemed to consider predominantly cellular in mediation (meaning driven by T cells) would be impacted (beyond general contentions weakly linking vaccine-induced cytokine upregulation to T helper cells).

Dr. Akbari possessed the necessary credentials to offer an opinion on the immunologic issues raised by Petitioner's causation theory. But that opinion was ultimately unreliable and unpersuasive. And I need not accept Dr. Akbari's say-so that the flu vaccine was likely causal. *Bender v. Sec'y of Health & Hum. Servs.*, No. 11-693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. July 2, 2018). Dr. Bates, by contrast, presented a more credible opinion that was better substantiated. Having heard both experts, I did not deem Dr. Akbari's opinion to be well-founded.

Second, Petitioner has not demonstrated his injuries had anything more than a (distantly) temporal association with vaccination, and thus he cannot meet the "did cause" *Althen* prong. There is little evidence that Petitioner experienced an initial aberrant reaction to receipt of the vaccine, beyond his own reports of the kind of immediate malaise common to vaccine recipients (but not necessarily reflective or predictive of chronic subsequent immune dysfunction or dysregulation). I cannot on this record find proof that Petitioner's immune system went into a dysregulated state post-vaccination. There are no testing results for the six-plus months in the post-vaccination period that would corroborate the contention that Petitioner was experiencing progressive immune dysfunction. And the evidence of hypothalamic harm is absent as well.[24]

At best, the record reveals instances in which *some* treaters discussed or considered a vaccination association, such as Dr. Mucha (albeit a year after vaccination, and independently of the Mayo Clinic's more detailed findings). *See, e.g.*, Ex. 5 at 16, 20. But they did not *consistently* do so, or the views about possible vaccine association were too speculative in quality. *Id.* (discussing March 23, 2018 visit at Health Partners and documenting resident's initial concern for a possible ongoing reaction to flu shot but noting how highly atypical that would be). At the same time, experienced and credentialed treaters at the Mayo Clinic, considering Petitioner's presentation along with the positive anhidrosis test, proposed his symptoms might be attributable to his indisputable preexisting conditions (like achondroplasia or cervical myelomalacia). Ex. 3 at 133. Dr. Donofrio also highlighted similar factors as more likely explanatory. Donofrio Rep. at 7.

Of course, claimants need not affirmatively *exclude* alternative factors that could explain an alleged vaccine injury. But they have *some obligation* to grapple with the record when it establishes the existence of such countervailing factors—and Petitioner failed here to do so. *M.R. v. Sec'y of Health & Hum. Servs.*, No. 16-1024V, 2023 WL 4936727, at *30 (Fed. Cl. Spec. Mstr. June 30, 2023). Ultimately, I cannot on this record determine *what* explanation for Petitioner's general complaints has the most preponderant support (and I do not *ever* purport to diagnose the cause of any Program claimant's injury in performing my duties as a special master). But the overall murkiness of this evidentiary balance prevents a finding that the flu vaccine was *itself* likely a substantial factor in causing anhidrosis.

Finally, the record does not support the conclusion that the timeframe from vaccination to onset of Petitioner's anhidrosis was medically acceptable. Indeed, it is not self-evident when Petitioner's anhidrosis *actually first manifested*—whether in comparison to the date of vaccination or Petitioner's positive TST result. I do not conclude that Petitioner's initial malaise reaction, close-in-time to vaccination, constituted onset, as those nonspecific symptoms are distinguishable from anhidrosis, and were likely unconnected to Petitioner's subsequently-reported cold

[24] Although Petitioner contends the imaging he underwent might not be able to detect this kind of harm to the brain, this is not necessarily the case, since Dr. Mucha *relied* on MRI imaging in informing Petitioner in April 2018 that he likely had *not* experienced a hypothalamic injury. *See, e.g.*, Ex. 8 at 26–28.

intolerance. Although Petitioner expressly testified he did not feel symptoms of anhidrosis before mid-2018, Dr. Jeret could only speculate that Petitioner may have experienced the symptoms sooner but did not so realize.

There is some record evidence that Petitioner first began complaining of cold intolerance that *could* be viewed as a manifestation of anhidrosis in January-February 2018. Thus, the record only possibly supports the conclusion that the October 2017 vaccination produced an adverse reaction that *at earliest* was evident no sooner than three to four months later. Moreover, Petitioner's experts did not contend that Petitioner's initial purported fibromyalgia evolved into anhidrosis or reflected its initiation, proposing instead that these injuries unfolded in parallel manner due to vaccination. And no evidence was presented that anhidrosis has a long prodromal phase, or is commonly preceded by the sorts of nonspecific complaints Petitioner asserts he first started to experience in the fall of 2017.

An onset of three or more months post-vaccination, however, is facially long, especially absent record evidence that suggests a developing condition progressing toward anhidrosis. Dr. Akbari in no way persuasively established that such a timeframe could be medically acceptable. *Bennenhaley v. Sec'y of Health & Hum. Servs.*, No. 20-0545V, 2022 WL 17974426, at *7 (Fed. Cl. Spec. Mstr. Dec. 28, 2022). And it was not demonstrated that Petitioner's series of somewhat nonspecific complaints constituted a slow progressive prodromal phase leading to his more obvious anhidrosis symptoms. Rather, the theory offered seems tailored to Petitioner's health experiences within a year of his vaccination.

CONCLUSION

Vaccine Act claimants must carry their burden of proof to be entitled to damages. Because Petitioner cannot show by preponderant evidence that his anhidrosis could be vaccine-caused, I deny entitlement.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[25]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[25] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.